

REMARKS/ARGUMENTS

Claims 53-80 are pending in the application of which all claims were rejected. By way of the present amendment, claims 53, 61, 62 and 64 have been amended, no claims have been canceled, and no claims have been added. No new matter has been added. Applicants request entry of this amendment and reconsideration of the pending claims given the amendments and remarks made herein.

Priority Claim

Applicants wish to thank the Examiner for acknowledging Applicant's priority claim to Application No. 10/637,713 filed on August 8, 2003. Applicants note, however, an apparent typographical error in the Office Action where application 10/637,713 is referenced as application 10/814,593 (page 2).

Claim Objections

Claims 53 and 64 were objected to by the Examiner regarding the use of certain claim terms (Office Action, page 3). Claims 53 and 64 have been amended to replace the term "unattached" with the term "not fixedly attached," as suggested by the Examiner. Accordingly, Applicants respectfully request the objection be withdrawn.

Claim Rejections - 35 USC §103

Claims 53, 54, 56-62, 64, 65, 67, 69-71 and 73-78 were rejected under 35 USC §103(a) as allegedly unpatentable over International PCT Application Publication 2002/0156496 in the name of Chermoni ("Chermoni") in view of US Patent Application Publication WO 03/022178 in the name of Andersen (hereinafter "Andersen") and further in view of US Patent Application Publication 2002/0193873 in the name of Brucker et al. ("Brucker") (Office Action, page 3). Such rejections are traversed in part and overcome in part as follows.

While Applicants respectfully disagree with the rejections and do not acquiesce to any reasoning provided in the Office Action, independent claims 53 and 64 have been amended to expedite prosecution. As will be set forth below for each of the independent claims, the combination of Chermoni with Andersen and Brucker fails to disclose all the elements as set forth in amended claims 53 and 64. Thus, Applicants maintain that the cited combination of references fail to establish a *prima facie* case of obviousness under § 103.

Amended independent claim 53 recites:

53. *A method of treating one or more lesions in a vessel, the vessel having a main branch and a side branch branching from the main branch at a bifurcation, the method comprising:*

*providing a plurality of stent segments comprising a first, second, and third stent segment, each segment being not fixedly attached with each other and **selectively axially separable from each other when unexpanded;***

*positioning a delivery catheter in the main branch, the delivery catheter having an expandable member disposed thereon, wherein at least two adjacent segments of the plurality of stent segments are **axially positionable** over the expandable member **and are in direct contact with one another when unexpanded;***

axially separating a first stent from a second stent when unexpanded, the first stent comprising the first and the second stent segments, and the second stent comprising the third stent segment;

radially expanding the expandable member thereby radially expanding the first stent, wherein expanding the first stent comprises expanding the first and second stent segments concurrently in the main branch;

positioning the delivery catheter in the side branch; and

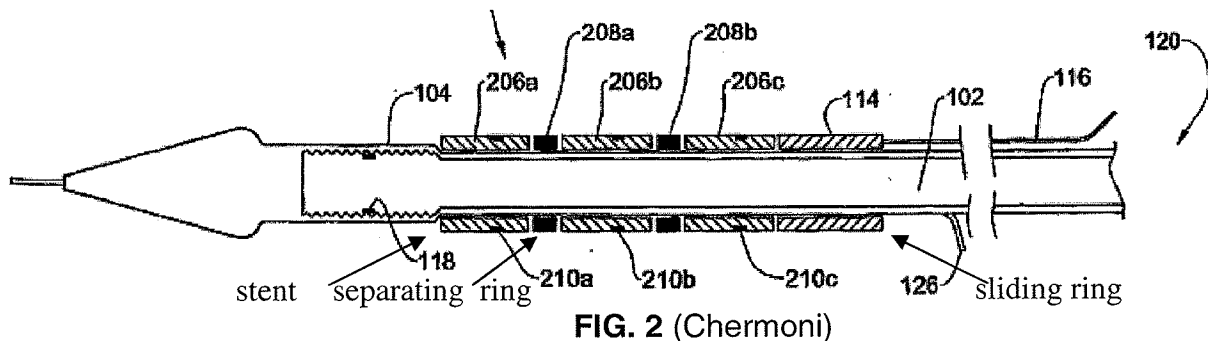
radially expanding the expandable member thereby radially expanding the second stent in the side branch, and

wherein the delivery catheter remains in the vessel between radially expanding the first and second stents.

Support for the amendments to claim 53 can be found throughout the specification as originally filed, and in particular in Paragraphs [0021] and [0037] and Figures 1 and 7A-7E of the application publication; therefore, no new matter has been added. Having a stent comprised of a plurality of selectively axially separable segments is advantageous as it allows for customization of the length of the stent to accommodate lesions of varying length. This feature allows for adjustment of the stent length *in situ* to match the size of the lesion to be treated, particularly useful since measurements of the size of a lesion prior to the stenting procedure may be inexact (Paragraph [0005]). Additionally, having a stent comprised of multiple segments where adjacent segments are in direct contact but not fixedly attached allows the stent to be highly flexible and capable of deployment in long tortuous lesions while minimizing axial foreshortening during deployment (Paragraph [0046]).

The combination of Chermoni, Andersen and Brucker fails to disclose at least a plurality of stent segments that are selectively axially separable from each other, adjacent

segments being axially positionable over the expandable member and in direct contact with one another when unexpanded, or axially separating a first stent (comprising a first and second segment) from a second stent, as recited in claim 53. Chermoni discloses separately deploying multiple stents separated by sliding spacer rings, as shown below in Figure 2 (Paragraphs [0032] and [0037]). Chermoni fails to disclose a plurality of stents having adjacent segments that are in direct contact and not fixedly attached and wherein each segment is selectively axially separable from each other when unexpanded. As shown in Figure 2, the segments of Chermoni are separated by separating rings and not in direct contact when unexpanded. Additionally, there is no apparent means in Chermoni to selectively axially separate segments from each other when unexpanded. Furthermore, there would be no reason to modify Chermoni to include these features since the stents are already separated by separated rings.

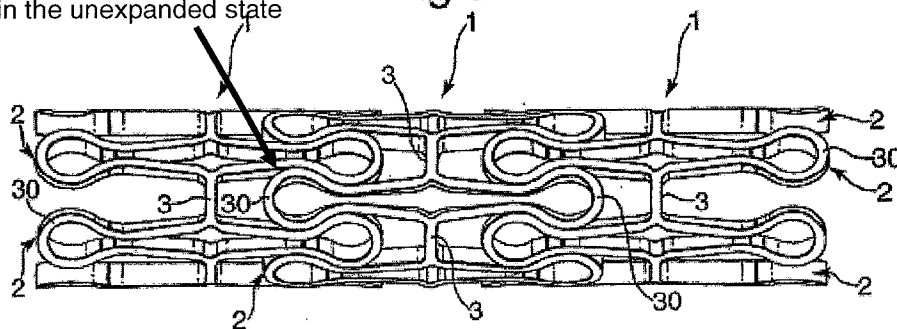


Andersen fails to disclose at least the elements of claim 53, discussed above, missing from Chermoni. Andersen discloses an expandable stent made up of a plurality of separate tubular elements (Abstract). Although the tubular elements are “separate,” adjacent elements are “interlocked” by loop and waisted portions on the extremities of each element *when unexpanded*, as shown below in Figure 6 (Abstract; p. 11, li. 27-p. 12, li. 27; Figs. 6-7). Applicants maintain that separate interlocking elements of a stent are distinguishable from a plurality of stent segments that are selectively axially separable from each other when unexpanded, as recited in claim 53. In fact, Andersen’s disclosure that the separate elements are *interlocked when unexpanded* to create a stable structure teaches away from modifying the separate elements to be selectively axially separable from each other when unexpanded or the

step of axially separating a first stent from a second stent when unexpanded, as recited in claim 53. Not only does the disclosure of Andersen fail to disclose the missing elements of claim 53, but modifying the plurality of segments in Anderson to include such elements would be counter to the teachings therein. Thus, Anderson teaches away from axially separating a first stent (comprising a first and second segment) from a second stent, as recited in claim 53.

interlocking loop and waisted portions in the unexpanded state

Fig.6. (Andersen)



Brucker fails to disclose at least the above-noted elements of claim 53 missing from Chermoni and Andersen. Brucker discloses a catheter system for delivering a bifurcated stent by separately deploying separate stent bodies to form a bifurcated assembly (Paragraph [0081]; Figs. 7 and 18-20). As shown for example in Figure 18, Brucker discloses separate stents 114 and 116 on separate “stent retaining regions” 118 and 120.

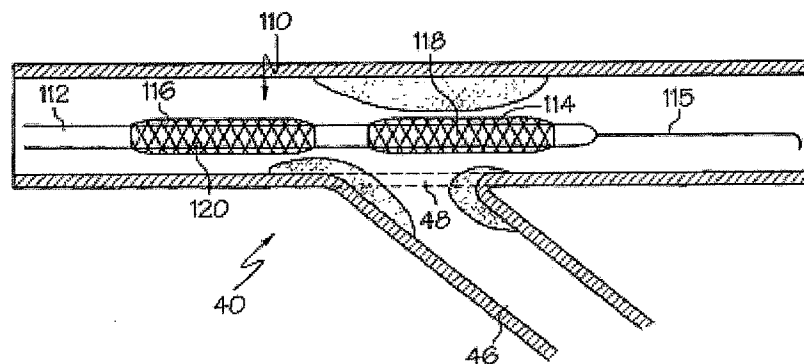


FIG. 18 (Brucker)

Nowhere does Brucker disclose a stent comprising a plurality of segments that are selectively axially separable from each other when unexpanded, as recited in claim 53. Stents on “stent retaining regions,” which are fixed to the catheter, cannot be selectively axially separated

from each other when unexpanded. To modify Brucker to allow the segments to be axially positionable or selectively axially separable when unexpanded would be counter to the function of the “stent retaining regions,” as taught in Brucker. Thus, Brucker teaches away from the claimed steps in claim 53. As the cited combination fails to disclose all elements of amended claim 53, a *prima facie* showing of obviousness has not been established. Therefore, Applicants respectfully submit that claim 53 is allowable over the cited combination of references.

Moreover, Applicants maintain that claim 53 is further allowable as there would be no reason to combine the cited references to perform the claimed method. As Chermoni and Brucker relate to separately deploying stents that are already separated by rings or retaining regions, and Andersen relates to a stent having separate segments that are interlocked when unexpanded, Applicants respectfully submit that there is neither a reason nor likely capability for combining or modifying the references to perform the method of claim 53. None of the cited references are suggestive of a first stent comprising a plurality of segments that are selectively axially separable when unexpanded, let alone the step of axially separating the first stent from a second stent when unexpanded, as recited in method claim 53. As noted above, these features allow for adjusting the length of a stent, a feature which none of the cited references suggest or are capable of performing. Even if a stent in Chermoni were modified to incorporate the separate segments of Andersen, as suggested on page 4 of the Office Action, such a modification would still not result in segments that are selectively axially separable when unexpanded, nor allow the step of axially separating a first stent from a second stent when unexpanded. Thus, Applicants maintain that the claimed method clearly cannot be a predictable result from combining the references as suggested. As the cited combination of references fails to disclose all the elements of claim 53, as well as a reason or likely capability to perform the claimed method, the references have not established *prima facie* obviousness. Accordingly, Applicants respectfully submit that amended claim 53 is allowable over the cited combination of references.

Claims 54, 56-62 and 73-75 depend, either directly or indirectly, from independent claim 53, which has been distinguished from the cited references as discussed above. Thus, for at least the same reasons as in claim 53, as well as on their own merits, Applicants maintain that these claims are allowable over the cited combination of references.

With regard to dependent claims 61 and 62, nowhere does the cited combination of references disclose adjusting the length of a stent before deployment. Notwithstanding, to further clarify this feature, claims 61 and 62 have been amended to recite that adjusting the length comprises selectively exposing a desired number of stent segments according to the length of the lesion to be treated. Support for this amendment is found throughout the application as-filed, and in particular in Paragraphs [0037]-[0040] and in Figures 1 and 7A-7E.

In rejecting claims 61 and 62, the Office Action relies on Chermoni as disclosing adjusting the length of a stent by arguing that “the stents may be delivered in any order and may be different length and so the lengths are adjusted by choosing a different order of stents” (page 4). Applicants respectfully disagree with this interpretation of “adjusting the length” of a stent and maintain that simply selecting a different stent having a different length is not analogous to “adjusting the length” of the first or second stent, as recited in claims 61 and 62, respectively. Although the device of Chermoni may include stents having different lengths, the lengths of the stents are clearly not adjusted before deployment, nor does the device allow for such adjustment. Neither does Chermoni suggest adjusting the length by selectively exposing a desired number of segments comprising the stent. Thus, Applicants maintain that claims 61 and 62, on their own merits, are further distinguishable from and allowable over the cited combination of references.

Independent claim 64 has been amended similarly as claim 53 and finds similar support. For at least reasons similar to claim 53, Applicants maintain that the combination of Chermoni, Andersen and Brucker fails to disclose all the elements of amended claim 64, as well as claims 65, 67, 69-71 and 76-78 ultimately depending from claim 64. Accordingly, Applicants respectfully submit that such claims are allowable over the cited combination of references.

Chermoni in view of Andersen and Brucker and further in view of Fischell

Claims 55, 66, 72, 79, and 80 were rejected under 35 USC §103(a) as allegedly unpatentable over Chermoni in view of Andersen and Brucker and further in view of US Patent No. 5,697,971 to Fischell et al. (hereinafter “Fischell”). Such rejections are traversed in part and overcome in part as follows.

Claims 55, 66, 72, 79 and 80 ultimately depend from either independent claim 53 or 64, both of which have been distinguished from Chermoni, Andersen and Brucker as discussed above. Fischell fails to disclose the elements of claims 53 and 64 missing from Chermoni, Andersen and Brucker. As the cited combination of references fails to disclose all elements of the rejected claims, *prima facie* obviousness has not been established. Therefore, Applicants respectfully request the rejections of claims 55, 66, 72, 79 and 80 be withdrawn.

Chermoni in view of Andersen and Brucker and further in view of Shaknovich

Claims 63 was rejected under 35 USC §103(a) as allegedly unpatentable over Chermoni in view of Andersen and Brucker and further in view of US Patent No. 5,807,398 to Shaknovich et al. (hereinafter "Shaknovich"). Such rejections are traversed in part and overcome in part as follows.

Claim 63 depends from claim 53, which has been distinguished from Chermoni, Andersen and Brucker as discussed above. Shaknovich fails to disclose the elements of claim 53 missing from Chermoni, Andersen and Brucker. As the cited combination of references does not disclose all elements of claim 63, *prima facie* obviousness has not been established. Therefore, Applicants respectfully request the rejection of claim 63 be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

Further, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account No. 20-1430.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-324-6349.

Respectfully submitted,



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